

Amendment and Reply

Atty. Dkt. No. P-5838

Serial No.: 10/660,760

Filing Date: September 12, 2003

Title: Methods of Surface Modification of a Flexible Substrate to Enhance Cell Adhesion

**REMARKS/ARGUMENTS****I. SUPPORT FOR THE CLAIM AMENDMENTS**

Claims 1, 3, 9, 17, 25, 28 and 29 have been amended, claims 8 and 24 have been canceled and claims 38-57 have been added. Claims 1, 17, 25, 28 and 29 have been amended to better capture the envisioned commercial embodiments and to correct dependency. Claims 3 and 9 have been amended to correct antecedent basis and dependency. Support for the claim amendments can be found throughout the specification and originally filed claims. Specifically, support for the amendments to claims 1, 17, 25, 28 and 29 can be found in at least originally filed claims 8 and 24 and paragraphs 0023, 0025, 0026, 0027 and 0028. Support for new claims 38-57 can be founding at least originally filed claims 1-37 and paragraphs 0014-0019, 0023-0028 and 0031-0033. Accordingly, no new matter has been introduced by way of these amendments and new claims.

**II. ALLOWABLE SUBJECT MATTER**

Applicants acknowledge the indication of allowable subject matter and wish to thank the Examiner for notification to that effect.

**III. THE REJECTIONS OF CLAIMS 1-7, 15-24 AND 32-37 UNDER 35 U.S.C. §§102(b) AND (e) ARE MOOT**

The Office Action of September 7, 2005 rejected claims 1-7, 15-24 and 32-37 under 35 U.S.C. §§102(b) and (e). Specifically, the Office Action alleges that Genzer (U.S. Pat. No. 6,423,372) anticipates claims 1-7, 15-24 and 32-37 under 35 U.S.C. §102(b). Without agreeing with the interpretation of Genzer set forth in the September 7<sup>th</sup> Office Action, Applicants have amended claims 1 and 17 to better capture the envisioned commercial embodiments. Applicants believe that Genzer never anticipated claims 1-7, 15-24 and 32-37, and that the amendments to claims 1 and 17, which flow through to their dependent claims, render moot the rejections of claims 1-7, 15-24 and 32-37 under 35 U.S.C. §102(b).

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Indeed, claim 1 and its dependent claims now include activating the exposed functional groups, and the Office Action states that neither of the Genzer references disclose that the functional group is activated (Office Action, page 10). Accordingly, it is Applicants' position that neither Genzer reference anticipates current claims 1-7, 15 and 16 because the Genzer references do not teach each and every limitation of the presently claimed invention.

Applicants have also amended claim 17 such that claim 17 and its dependent claims now specify that the cell adhesive-molecule is an extracellular matrix molecule, an antibody or antigen-binding fragment thereof or a growth factor. The Office Action states that neither of the Genzer references disclose the use of an extracellular matrix molecule, an antibody (or fragment thereof) or a growth factor. (Office Action, page 13). Accordingly, it is Applicants' position that neither Genzer reference anticipates current claims 17-24 and 32-37 because the Genzer references do not teach each and every limitation of the presently claimed invention. Reconsideration and withdrawal of these rejections under 35 U.S.C. §102(b) and (e) are earnestly solicited.

**IV. THE REJECTIONS UNDER 35 U.S.C. §103 ARE MOOT OR TRAVERSED****A. THE REJECTION OF CLAIM 8 UNDER 35 U.S.C. §103 IS MOOT**

The Office Action of September 7, 2005 rejected claim 8 as allegedly "being obvious over Genzer et al. (U.S. Pat. No. 6,423,372 or 6,770,323) in view of Klaerner et al. (U.S. Pat. No. 6,692,914)." (Office Action, page 9). Applicants have canceled claim 8, rendering moot the rejection of claim 8.

Applicants assert, however, that the Genzer and Klaerner did not render obvious previously pending claim 8. To establish a case of *prima facie* obviousness, three criteria must be met. First, the cited references must teach *every* limitation of the currently claimed invention, *In re Royka* 490 F.2d 981, 985 (C.C.P.A. 1974). Second, there must be some suggestion or motivation in the references themselves, or within the knowledge of one of ordinary skill in the art, to combine the references to arrive at the claimed invention. Lastly, there must be a

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reasonable expectation of success in combining the references, and that this expectation of success is found in the references as well. *In re Vaack* 947 F.2d 488, 493 (Fed. Cir. 1991).

The cited references, alone or in combination fail to meet the criteria necessary to establish a *prima facie* case of obviousness. For example, there is no motivation to combine the cited references to arrive at the claimed invention with any reasonable expectation of success. Indeed, the Office Action does not state why one of skill in the art would be motivated to modify the teachings of Genzer with Klaerner; nor does the Office Action demonstrate that there would be any reasonable expectation of success in modifying Genzer with Klaerner to arrive at the claimed invention. And “[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done.” (MPEP, §2142, 8<sup>th</sup> Ed. October 2005) (emphasis added).

The cited references themselves do not provide the requisite motivation for their combination, nor do the references create any *a priori* expectation that the claimed invention could successfully be formulated. In fact, a careful reading of the Klaerner and Genzer would militate against combining the disclosures to arrive at the claimed invention. Indeed, Klaerner discusses the difficulties associated with increasing the grafting density of polymers on a surface. For example, Klaerner states that “as the grafting density continues to increase, eventually chains are close enough to become entangled and otherwise sterically hinder the functional group-bearing sites, thereby limiting the ability to attach a probe molecule to the polymer chain at these sites;” (USPN 6,692,914, col.5, ll.18-22). In addition, Klaerner states that “once probes are bound to the surface, they must remain accessible to components of the biological sample. Here too, factors such as steric hindrance may hamper accessibility.” Thus, while Klaerner may discuss particular chemistries, Klaerner also teaches that there are functional limits for grafting densities on surfaces. Taken as a whole, therefore, Genzer and Klaerner would suggest to one of skill in the art that, while in theory it may seem desirable to increase the grafting density of polymers, increasing the grafting density would actually create problems downstream.

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Furthermore, there is no indication that the chemistry described in Klaerner could successfully be applied to polymeric surfaces comprising functional groups.

After reading Genzer and Klaerner, therefore, one of ordinary skill art would not have considered obvious the claimed process of producing a surface with enhanced cell-adhesive properties. The person of ordinary skill, informed by Genzer and Klaerner, would have felt, at most, that it was *obvious to try*, somehow, to prepare a surface with enhanced cell-adhesive properties. Obvious-to-try, however, is not the proper standard for an obviousness analysis.

Accordingly, no reading of Genzer and/or Klaerner, against the background of the prior art as a whole, could have led the skilled artisan to select a process for producing a surface with enhanced cell-adhesive properties as presently claimed. Therefore, the pending obviousness rejection should be withdrawn.

**B. THE REJECTION OF CLAIMS 9-14 UNDER 35 U.S.C. §103 IS TRAVERSED**

The Office Action of September 7, 2005 rejected claims 9-14 as allegedly "being unpatentable over Genzer et al. (U.S. Pat. No. 6,423,372 or 6,770,323) in view of Klaerner et al. (U.S. Pat. No. 6,692,914) and Hendriks et al. (Pub No.: US 2003/0035786)." (Office Action, page 11).

As discussed above, Genzer and Klaerner do not render obvious the claimed invention, and Hendriks does not rectify their inapplicability to the present invention. Again, even though Hendriks may discuss particular chemistries, neither Genzer nor Klaerner nor Hendriks creates any expectation of success in obtaining the claims methods. As discussed above, one of skill in the art would have no reason to expect that a polymeric surface with enhanced cell-adhesive properties could be created by combining methods disclosed in the cited references. At best, the references may suggest an attempt to create such a surface, but obvious to try is not the standard for an obviousness analysis. Accordingly, applicants assert that Genzer and Chen do not render the claimed invention unpatentable under 35 U.S.C. §103. Withdrawal of the obviousness rejection is earnestly solicited.

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**C. THE REJECTION OF CLAIMS 25-29 UNDER 35 U.S.C. §103 IS TRAVERSED**

The Office Action of September 7, 2005 rejected claims 25-29 as allegedly “being unpatentable over Genzer et al. (U.S. Pat. No. 6,423,372 or 6,770,323) in view of Chen et al. (Pub No.: US 2002/0182633).” (Office Action, page 13).

Once again, there appears to be motivation for combining the references to arrive at the claimed invention. And the “suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.” *In re Rouffet* 149 F.3d. 1350, 1358 (Fed. Cir. 1998). Indeed, it appears that the combination of cited references is nothing more than an attempt to use the Applicants’ claimed invention as a blueprint for piecing together prior known elements. And to prevent the use of hindsight analysis, “the examiner [is required] to show a motivation to combine the references that create the case for obviousness.” *In re Rouffet* at 1357.

To that end, neither the references nor the nature of the problem to be solved provide any motivation for combining Genzer and Chen to arrive at the claimed invention. The cited references themselves do not provide adequate motivation for their combination and the Office Action does not point to any rationale contained in the references that would militate combining Genzer and Chen to arrive at the claimed invention. Accordingly, applicants assert that Genzer and Chen do not render the claimed invention unpatentable under 35 U.S.C. §103. Withdrawal of the obviousness rejection is earnestly solicited.

**CONCLUSION**

Claims 1, 3, 9, 17, 25, 28 and 29 have been amended, claims 8 and 24 have been canceled and claims 38-57 have been added. Support for the claim amendments and new claims can be found throughout the specification and originally filed claims, thus no new matter has been introduced into the pending application.

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In view of the amendments to the claims, Applicants assert that the rejections under 35 U.S.C. §102(b) and (e) are moot. In addition, Applicants request that the rejections under 35 U.S.C. §103 be withdrawn, in light of the arguments presented herein.

Should the Examiner believe that further discussion of any remaining issues would advance the prosecution, he or she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date

March 3, 2006

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being facsimile transmitted or being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3<sup>rd</sup> day of March, 2006

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